

REMARKS

Claims 1-17 are currently pending in the present Application, following withdrawal of claims 18-49 pursuant to the May 10, 2004 Requirement.

Claims 1-17 stand rejected under § 102(b) as anticipated by U.S. Patent No. 5,628,960 to Beer, *et al.* ("Beer") or U.S. Patent No. 4,894,157 to Johnson ("Johnson"). The Applicants respectfully traverse these rejections on the grounds they do not disclose the features of the present invention recited in the pending claims.

The Present Invention: Claim 1 recites a process for producing a cellulose membrane having a refined surface, in which a feedstock membrane is prepared from a cellulose membrane casting solution by phase inversion in an evaporation process, and impurities are removed from newly formed membrane *after* the cellulous membrane layer has been formed, but before the membrane is completely dried. *See, e.g.,* Specification at 4:6-32 (describing formation of the membrane as in the prior art, followed by bringing the membrane into contact with cleaning agents or devices to remove filter dust, preferably while the membrane still contains 5-20% of the originally present solvent from the membrane casting process).

In contrast, in the prior art the general approach to eliminating filter dust was to process the membrane feedstock materials to precipitate out contaminates *before* the membrane was formed. *See,* Specification at 2:27-32 ("A prior art process for eliminating [dust formation] consists of reprecipitating commercially available feedstocks ... prior to using such feedstocks in the

manufacture of the membrane.”) This prior art approach has a number of disadvantages, including its being a complex multi-phase process, and the cost and inefficiency associated with such “purification” of the feedstocks. *Id.* The present invention’s post-membrane formation approach to filter dust treatment eliminates these concerns by eliminating the need for pre-processing of the feedstocks.

The cited Beer reference is an example of the prior art approach, and does not disclose the present invention’s dust removal *after* membrane formation. In fact, the cited portion of this reference (Beer at 3:45+) is quite specific in this regard: “*Prior to adding the cellulous derivatives to the polymeric blend solution [from which the membrane is formed], they were first dissolved in acetone and methylene chloride and reprecipitated* by the addition of methanol and water to remove extraneous non-membrane forming substance which are responsible for the creation of “filter dust.” Beer at 3:49-54 (emphasis added). A description of the membrane casting process follows this pre-casting purification of the feedstock materials. Beer at 3:54-66. Thus, the use of methanol and water in Beer is not a post-membrane formation cleaning step, but part of the pre-treatment of the feedstock materials.

Because the Beer reference teaches pre-membrane refinement of feedstocks to remove dust-forming impurities before the membrane is cast (*i.e.*, before the dust is even formed), this reference does not disclose the present invention’s removal of filter dust after the membrane has been formed and before it is dried. The pending claims are therefore patentable over Beers under

§ 102(b). Reconsideration and withdrawal of the pending rejection based on Beers is respectfully requested.

With regard to the Johnson reference, as a first matter the Applicants respectfully submit that this reference is not analogous art with respect to the present invention. Johnson relates to a supported microporous membrane filter for the filtration of biological fluids. Johnson at 1:6-10; 2:29-40. In such filters one part of the fluid passes through from one side of the filter to the other by passing through the pores of the membrane and the supporting materials. In contrast, the present invention is directed to diagnostic assays in which there is no flow *through* the membrane, but instead lateral flow across the surface of the membrane. In the Johnson technology, accumulation of filter dust on the membrane is not of significant concern, as such dust is readily removed during a test by the fluid, which causes the dust to pass *through* the pores.

Unlike Johnson, where the presence of dust has little or no effect on the test results, the presence of accumulated filter dust diagnostic assay membranes leads to inhomogeneous lateral flow across the membrane surface, which can lead to imprecise, faded and/or distorted test results. In view of the lack of significant concern with dust formation in cross-flow filters, one of ordinary skill in the art would not have looked to cross-flow filters such as in Johnson when seeking to solve lateral-flow membrane filter dust accumulation problems.

As a separate grounds for traverse, the Applicants submit that Johnson does not disclose or suggest the present invention's formation of a membrane by the recited phase inversion process, *followed by removal of impurities by contact*

with cleaning agents or devices before the membrane is dry. Rather, Johnson discloses an optional rinsing step which is taught as only “serv[ing] to speed up the removal of residual *solvents* from the semi-solid *membrane* on the support web 42,” a process which “has the added benefit of reducing the dwell time in the gelation chamber 22.” Johnson at 7:12-17.

Thus, Johnson teaches only accelerated removal of the process solvents used to form the membrane -- a material which is not an “impurity” in the process chemicals, but a process chemical itself. *Accord* Johnson at 2:64-67 (description of the rinse in the Johnson summary, noting the materials being removed are “residual *non-polymeric* components of the casting lacquer” – unlike the filter dust addressed by the present invention, which is a *polymeric* material). Ultimately, review of Johnson reveals that there is simply no reference to filter dust or dust removal of the sort recited in the present invention.

Because Johnson is non-analogous art, and further because Johnson does not disclose the removal of filter dust in the manner recited in claim 1, the Applicants respectfully submit that claims 1-17 are not anticipated by Johnson under § 102. Reconsideration and withdrawal of the pending rejection based on Johnson is respectfully requested.

Reconsideration of the Restriction Requirement is Requested.

The Applicants request the Examiner’s further reconsideration of the restriction requirement.

In the Election/Restriction Requirement, the Examiner maintained that

the Group III apparatus for refining a surface of the recited membrane can be used for making a different product, “such as a cellulose membrane that does not have a refined surface.” May 10, 2004 Requirement at 2-3. The Applicants respectfully note that the Group III apparatus cannot produce a membrane with an unrefined surface. The apparatus requires a membrane cleansing device “for bringing ... the feedstock membrane ... *into contact with*” a cleansing agent or device. Claim 35. Thus, the product produced with the Group III apparatus will *always* be a refined surface membrane. Because the Group III apparatus cannot be used to making a different product, Group III should not be restricted from Groups I, II.

As to Group II, it is asserted in the May 10, 2004 Restriction that the product of claims 18-34, the recited surface refined membrane, can be prepared by a materially different process, “such as one that includes reagents for determining the presence or absence of an analyte.” May 10, 2004 Restriction at 2. The Applicants respectfully submit that the Examiner’s justification for the restriction of Group II does not describe any materially different *process* for generating the same product. In fact, no alternative process is identified in the Requirement. Rather, the “process” set forth is merely descriptive of the resulting *product* (a membrane “that includes reagents for determining the presence or absence of an analyte”). Because the threshold demonstration of the existence of a materially different process from which the claimed product can be produced has not been met, the Applicants respectfully submit the restriction of Group II cannot stand. And in any event, the addition of reagents would not

create a "materially different" process, it would merely add a step to the underlying process which *must* be used to form this product. In order to obtain the claimed surface refined membrane, *i.e.*, a membrane which has had dust removed *after* it is formed, the membrane surface *must* be contacted by a cleaning agent or device. The Applicants respectfully submit that because the claimed process must be used to form the claimed product, the restriction between Groups I and II is inappropriate.

In view of the foregoing, the Applicants respectfully request the restriction of claims 18-49 be reconsidered and withdrawn.

CONCLUSION

The Applicants respectfully submit that claims 1-17 are in condition for allowance. Early and favorable consideration, and issuance of a Notice of Allowance for these claims is respectfully requested. The Applicants further request withdrawal of the restriction of claims 18-49, and allowance of these claims with claims 1-17.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit

Account No. 05-1323 (Docket #010743.50685US).

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Respectfully submitted,



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